

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

This Information Disclosure Statement accompanies the new patent application submitted herewith of the following Inventors: Eric Joel BENJAMIN; Maysara Saleh RABAH;

For: **STABILIZED PHARMACEUTICAL COMPOSITION CONTAINING BASIC EXCIPIENTS.**

1. Preliminary Statements

In accordance with 37 CFR 1.97 and 1.98, Applicants submit herewith patents, publications, or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) the information is material to the examination of this application; (iii) additional information material to the examination of this application does not exist; (iv) the information, protocols, results and the like reported by third parties are accurate or enabling; or (v) the information constitutes prior art to the subject invention.

2. ☐ Previously Cited Information

No copy of the patents, publications or other information cited on the attached form PTO-1449 is enclosed because it has been previously cited by or submitted to the Office in a prior application which is relied upon for an earlier filing date under 35 USC 120. Prior application is Application Number \_\_\_\_\_ filed on \_\_\_\_\_ of \_\_\_\_\_ for \_\_\_\_\_.

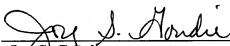
**CERTIFICATE OF MAILING 37 CFR §1.10**

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EU673381893US addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

September 30, 2003  
Date

Anna Weinberger-Pinkus  
Anna Weinberger-Pinkus

3. ☒ Newly Cited Information  
A legible copy of the patents, publications or other information cited on the attached form PTO-1449 is enclosed, except that no copy of a pending U.S. application is enclosed.
4. ☐ Concise Explanation  
Documents cited above which are not in the English Language  
a. ☐ have been explained in the specification.  
b. ☐ have an abstract (or other concise explanation) in English enclosed or, if readily available, a translation into English of the document is enclosed.
5. Form PTO-1449 is enclosed in duplicate.
6. Customer Number 25291.

  
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| Substitute for form 1449/PTO  |   |    | <b>C mplete if Known</b> |                        |          |
| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br><br>(use as many sheets as necessary) |   |    | Application Number       | AM101003               |          |
|   |   |    | Filing Date              | September 29, 2003     |          |
|   |   |    | First Named Inventor     | Eric Joel Benjamin     |          |
|   |   |    | Group Art Unit           |                        |          |
|   |   |    | Examiner Name            |                        |          |
| Sheet   | 1 | of | 1                        | Attorney Docket Number | AM101003 |

### U.S. PATENT DOCUMENTS

| Examiner<br>Initials* | Cite<br>No. | U.S. Patent Document |                         | Name of Patentee or Applicant<br>of Cited Document | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
|-----------------------|-------------|----------------------|-------------------------|--|--|--|
|                       |             | Number<br>(If known) | Kind Code<br>(If Known) |  |  |  |
|                       | 1.          | 6,002,008            |                         | Wissner et al.                                     | 12-14-1999   |  |
|                       | 2.          | 5,879,708            |                         | Makino et al.                                      | 03-09-1999   |  |
|                       | 3.          | 4,743,450            |                         | Harris et al.                                      | 05-10-1988   |  |
|                       | 4.          | 4,382,091            |                         | Benjamin et al.                                    | 05-03-1983   |  |
|                       | 5.          |                      |                         |  |  |  |

### FOREIGN PATENT DOCUMENTS

| Examiner<br>Initials* | Cite<br>No. | Foreign Patent Document |                 |                         | Name of Patentee or<br>Applicant of Cited document | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T                        |
|-----------------------|-------------|-------------------------|-----------------|-------------------------|--|--|--|--------------------------|
|                       |             | Office                  | Number          | Kind Code<br>(If Known) |  |  |  |                          |
|                       | 6.          |                         | EP 0 475 482 A1 | EP                      | AKZO N.V.  | 08-03-1992   |  | <input type="checkbox"/> |
|                       | 7.          |                         | EP 0 475 482 B1 | EP                      | AKZO N.V.  | 03-18-1992   |  | <input type="checkbox"/> |
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|                       | 13.         |                         |                 |                         |  |  |  | <input type="checkbox"/> |
|                       | 14.         |                         |                 |                         |  |  |  | <input type="checkbox"/> |

### OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS

| Examiner<br>Initials* | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T                        |
|-----------------------|-------------|---|--------------------------|
|                       |             |   |                          |
|                       | 15.         | M.L. Cotton et al, 1994, L-649,923-The selection of an appropriate salt form and preparation of a stable oral formulation, International Journal of Pharmaceutics, 109, 237-249.,   | <input type="checkbox"/> |
|                       | 16.         |   | <input type="checkbox"/> |
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|                       | 36.         |   | <input type="checkbox"/> |

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|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.